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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,183

Applicant(s)

DIB, NABIL

Examiner

Aamer S. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/01/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 2-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ouchi U.S. Patent Publication 2001/0004676 A1.

In regards to claim 21, Ouchi discloses a medical device including a catheter (30) for taking a biopsy of body tissue, the catheter (30) comprising a catheter lumen (see figure 2); and a needle (10) having an outer surface, a pointed end (see figure 1) for insertion into body tissue and a first port (12), open to the outer surface, the needle (10) movable from a first position to a second position (page 4 paragraph 68), the first port (12) being positioned in the catheter lumen when the needle (10) is in the second position, wherein when the catheter (30) is used the pointed end and first port are inserted into the body tissue (page 5 paragraph 87) when the needle is moved into the second position in order to collect biopsy material from the body tissue.

In regards to claims 2-4 and 8, Ouchi discloses that the device further includes a sheath (90) having a sheath lumen through which the catheter (30) is selectively moved (page 4 paragraph 68); a means (50) for selectively restricting relative movement between the sheath (90) and the catheter (30) (page 4 paragraph 71), a driver (70) for selectively moving the needle (10) with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the body tissue (page 5 paragraph 87); including an internal passage (13) in

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communication with the first port (12) and further including a second port (12) in fluid communication with the internal passage (13) and the first port (12) to retrieve the biopsy material from the first port (12).

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ouchi U.S. Patent Publication 2001/0004676 A1.

In regards to claim 17, Ouchi discloses a medical device for taking a biopsy of material, the medical device comprising a catheter (30) having a catheter lumen (see figure 2) with a proximal end and a distal end; a needle (10) with a pointed end for insertion into a body material (Page 5 paragraph 87), and a port (12) for receiving biopsy material the needle (10) for selectively moving to extend from the distal end of the catheter lumen to a first position (page 4 paragraph 68) wherein the pointed end and port are inserted into the body material to take the biopsy and (page 5 paragraph 87); retract to a second position wherein at least the port (12) is positioned within the catheter lumen (see figure 2), a sheath (90) having a sheath lumen through which the catheter (30) is selectively moved; and a driver (70) for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material.

In regards to claim 18, Ouchi discloses that the device further includes a means (50) for selectively restricting relative movement between the sheath (90) and the catheter (30) (page 4 paragraph 71).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi in view of Altman U.S. Patent Number 6,102,887. Ouchi describes the medical device as described in reference to claim 21, along with a driver. Ouchi fails to disclose that the driver selectively rotates the needle.

Altman discloses that, the driver selectively rotates the needle. (See Figure 5 and Column 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Ouchi by adding the rotating needle as taught by Altman in order to obtain a more controllable biopsy injection catheter.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi in view of Zadini et al U.S. Patent Number 5,312,361. Ouchi discloses the medical device as

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described above in reference to claim 21. However Ouchi fails to disclose that the medical device includes a sensor or that the sensor is on the needle.

Zadini et al describes a similar medical device with a sensor on the needle, 952. (See Figure 53).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Ouchi by adding the sensor as taught by Zadini et al in order to obtain a more controllable biopsy injection catheter.

Claims 22, 10-13, 16, 19 and 20 are under 35 U.S.C. 103(a) as being unpatentable over Altman in view on Ponzi U.S. Patent Number 6,575,931.

In regards to claim 22 Altman discloses a medical device for injecting a fluid into a material, the medical device comprising a catheter (402) having a catheter lumen; and a needle (410) having an outer sidewall, a pointed end for insertion into body tissue, a first port open, and an internal passage in communication with the port, wherein the pointed end and port are inserted into the body tissue and fluid is injected into the body tissue through the port (See Figures 4a and 4b). Altman fails to disclose that the port is open to the outer side wall.

Ponzi discloses a similar device with a port open to the outer side wall (45).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Altman by adding the port on the outer side wall of the needle as taught by Ponzi in order to enhance the ability of the drug or other agent passing through the needle to weep into the injection side and be more evenly distributed, allowing for better absorption (col. 7 line 17).

In regards to claims 10, Altman discloses that the medical device includes a sheath with a sheath through which the catheter is selectively moved, 424. (See Figures 4a and 4b).

Furthermore, as to Claims 11 Altman teaches the presence of a means for selectively restricting relative movement between the sheath and the catheter, 422. (See Figures 4a and 4b).

Also, as to Claim 12 Altman describes a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material, 420. (See Figure 4a).

Moreover, as to Claim 13 Altman discloses that, the driver selectively rotates the needle. (See Figure 5 and Column 7).

In addition, as to Claim 16 Altman teaches the presences of a second port in fluid communication with the first port and a supply of the fluid, 502. (See Figure 5).

In regards to claim 19, Altman discloses a medical device for injecting a fluid into a body material, the medical device comprising a catheter (402) having a catheter lumen with a proximal end and a distal end; a needle (410) having a side wall, a tip, the needle for selectively moving to extend from the distal end of the catheter lumen to a first position to inject the fluid into the body material through the port in the side wall; and retract to a second position within the catheter lumen; a sheath having a sheath lumen through which the catheter is selectively moved; and a driver for selectively moving the needle with one or more of a predefined force, a predefined acceleration and a predefined velocity to penetrate the material (See Figures 4a and 4b).

In regards to claim 20, Altman disclose the device includes a means for selectively restricting relative movement between the sheath and the catheter (See Figures 4a and 4b).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view on Ponzi and further in view and Zadini et al.

Altman describes the devices as described above in reference to Claim 22. However Altman fails to disclose a sensor, nor that the sensor is on the needle.

Zadini describes a similar medical device with, a sensor on the needle, 952. (See Figure 53).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the medical device of Altman and Ponzi by adding the driver and sensor as taught by Zadini in order to obtain a more controllable injection catheter.

Response to Arguments

Applicant's arguments with respect to claims 2-19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4953558 A	Akerfeldt; Dan
US 5989197 A	Avaltroni; Paolo
US 5425376 A	Banys; Algis R. et al.
US 6273861 B1	Bates; James S. et al.
US 6156006 A	Brosens; Ivo et al.
US 20020026126 A1	Burdorff; Mark A. et al.
US 5368045 A	Clement; Thomas P. et al.
US 6106524 A	Eggers; Philip E. et al.
US 6835193 B2	Epstein; Stephen et al.
US 6203556 B1	Evans; Douglas G. et al.
US 20020151850 A1	Ferguson, F. Mark et al.
US 5011490 A	Fischell; Robert E. et al.
US 4708147 A	Haaga; John R.
US 5477862 A	Haaga; John R.
US 5564436 A	Hakky; Said I. et al.
US 5810836 A	Hussein; Hany et al.
US 4781202 A	Janese; Woodrow W.
US 5611352 A	Kobren; Myles S. et al.
US 20020099307 A1	Krause; William R. et al.
US 6117130 A	Kung; Robert T. V.
US 5287857 A	Mann; David
US 4763667 A	Manzo; Michael P.
US 20020095124 A1	Palasis; Maria et al.
US 5964757 A	Ponzi; Dean M.
US 6540725 B1	Ponzi; Dean M.
US 6287301 B1	Thompson; Russell B. et al.
US 4702260 A	Wang; Ko Pen
US 5599300 A	Weaver; George W. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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